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Application No.: 10/821078

Case No.: 56630US007

REMARKS

Claims 58 to 75 are pending. Claims 76-81 are new. Reconsideration of the application is requested.

§ 102 Rejections

Claims 58-60 and 62-75 stand rejected under 35 USC § 102(e) as being anticipated by Dischler (U.S. Patent No. 6,585,693). Applicants respectfully disagree. MPEP 2131 states "To anticipate a claim, the reference must teach every element of the claim." Applicants argue that Dischler does not teach every element of the claimed inventions. At a minimum, Dischler fails to teach or disclose a barrier layer or container that is "substantially impermeable to ethylene oxide" as claimed in Applicants' independent claims 58 and 73.

First, Applicants submit that the Examiner has failed to establish that claims 58-60 and 62-75 are anticipated by Dischler (U.S. Patent No. 6,585,693). The Examiner appears to suggest that a polymer's impermeability to ethylene oxide is indicated by that polymer's permeability to water vapor. First, the Examiner cites no technical reference in support of this conclusion. Further, Applicants submit that one skilled the art would consider the opposite to be true, i.e., a polymer's solubility to water vapor is not an indication of the same polymer's solubility to ethylene oxide. See, for example, <http://plastics.dow.com/plastics/ap/techcenters/saran/perf/perm.htm>.

Second, the Examiner appears to be concluding that all of the polymer substances disclosed in Dischler are inherently impermeable to ethylene oxide. Dischler's device comprises a container that holds a solution of alcohol for preparing a skin site for injection. The container is formed from polymeric layers that may comprise one or more polymeric lamina, at least one lamina of which may be a barrier lamina. According to Dischler, a number of polymers may be used for the polymeric barrier layer of his invention, including, ethylene/vinyl alcohol copolymer (EVOH), polyvinylidene chloride (PVDC) and polyacrylonitrile (PAN), polyethylene, polypropylene, polycarbonate, nylon, polyester, PVC, EVA and copolymers and blends thereof. Dischler states, "These polymers are exemplary only, and *any polymeric or other flexible material* may be used as a barrier consistent with the stability of the medicament, the storage time required, compatibility with the medicament, and any other particular requirements" (column 1, lines 51-55; emphasis added).

Applicants refute this conclusion with evidence provided in Applicants' specification. High-density polyethylene (HDPE) is one example of a polymer that is used to make containers to store

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ethanol/water solutions for hand antiseptic applications. As shown in Example 3 of Applicants' specification, 17mil HDPE bottles permitted the penetration of relatively high (>300 ppm) levels of ethylene oxide and, thus, do not meet the requirement for substantial impermeability to ethylene oxide, as claimed in the present invention. In contrast, Applicants have shown that the HDPE ampoules having a thickness of 100mil (2540 microns) proved to be excellent barriers of ethylene oxide. See also Example 1 comparing ethylene oxide permeability of various polymer layers.

Although Dischler discloses an article to contain and dispense a skin antiseptic composition and that the article can be made from use of polymeric materials with chemical compositions similar to those of the present invention, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic.

Dischler did not recognize an essential problem solved by the present invention. The problem is stated on page 3, lines 27-32 of the Applicants' specification: "Reactive sterilants such as ethylene oxide may react with the active antimicrobial agent or with other components in the skin antiseptic composition altering the potency or producing potentially toxic compounds. For example, iodine, as well as other antimicrobial agents, potentially react with ethylene oxide that passes into the container during sterilization of the exterior surfaces of the dispensers. The effectiveness of such skin antiseptic compositions may be compromised by exposure to ethylene oxide gas."

As Dischler does not teach or suggest the problem, Dischler cannot provide the solution. Inherency may not be established by probabilities or possibilities. The MPEP states that, "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." The Dischler reference does not grasp the potential effects of ethylene oxide sterilization on skin antiseptic compositions and, as such, it does not teach or anticipate the materials and/or constructions needed to minimize the penetration of ethylene oxide into an article containing a skin antiseptic composition. In light of the Applicant's teaching of the problems associated with ethylene oxide, which is not taught or disclosed in Dischler, it is improper to conclude that the barrier layers and/or containers that are "substantially impermeable to ethylene oxide" as claimed by Applicants are inherent in Dischler.

Applicants also dispute that the fill port 52 of Dischler anticipates the claimed vent opening into the interior of the container of Applicants' claim 65. Dischler's fill port 52 is used to dispense reagents into the container 42, after which it is sealed (seal 50) and can no longer serve to vent, i.e.

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permit the passage of air, into the container 42. Applicants' vent assembly 30 allows for *simultaneous* flow of liquid out of the container and air into the container through *separate* openings.

For at least the above reasons, the rejection of claims 58-60 and 62-75 under 35 USC § 102(e), as being anticipated by Dischler, has been overcome and should be withdrawn.

§ 103 Rejection

Claim 61 stands rejected under 35 USC § 103(a) as being obvious over Dischler (U.S. Patent No. 6,585,693). The Examiner acknowledges that Dischler fails to disclose the skin antiseptic compositions claimed by Applicants' but argues that it would be obvious to one skilled in the art to modify Dischler with the compositions claimed by Applicants. Even assuming for purposes of argument that the Examiner's position was true (which Applicants do not admit), the modification of the Dischler reference would still not cure the deficiencies identified above, i.e., Dischler fails to teach or disclose all elements of Applicants' claim 61. Accordingly, the rejection of claim 61 under 35 USC § 103(a) as being unpatentable over Dischler has been overcome and should be withdrawn.

Summary

In summary, the rejection of claims 58-75 has been overcome and should be withdrawn. Claims 76-81 each add additional features to claims 58 and 73 and, as such, are in a condition for allowance.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Respectfully submitted,

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Date

By: Nancy M. Lambert
Nancy M. Lambert, Reg. No.: 44,856
Telephone No.: 651-733-2180

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833